

## REMARKS

After entry of this Amendment, the pending claims are claims 1, 3, 5, 7-11, 14-16, 24 and 25. The Office Action dated April 30, 2008 has been carefully considered. Claims 2, 4, 6, 12, 13, and 17-23 have been canceled without prejudice. Claims 1, 3, 5, 7-11, 14-16 have been amended and claims 24 and 25 are new. Support for the amendments to claim 1, 3, 5, 7-11, 14-16 and for new claims 24 and 25 can be found throughout the Specification and Figures and specifically in paragraph Nos. 0027-0031 and Figs. 1-5. Accordingly, no new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Office Action, dated April 30, 2008 the Examiner:

- rejected claims 1, 2, 4-10 and 14-22 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,578,034 to Estes ("Estes");
- rejected claims 1, 2, 4-10 and 12-15, and 17-22 under 35 U.S.C. § 102(b) as being anticipated by U.S. Publication No. 2001/0021851 to Eberlein et al. ("Eberlein");
- rejected claims 3 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Estes in view of U.S. Pat. No. 5,108,399 to Eitenmuller et al. ("Eitenmuller"); and
- objected to the drawings under 37 CFR 1.83(a) as failing to show all of the features of claims 21 and 22.

## DRAWINGS

The drawings were objected to under 37 CFR 1.83(a) for failing to show every feature of the invention specified in claims 21 and 22. Without addressing the merits of the Examiner's rejection, it is

respectfully submitted that claims 21 and 22 have been canceled without prejudice to expedite prosecution of the present application. As such, it is believed that this objection as to these claims is now moot. Withdrawal of this objection is respectfully requested.

#### **INDEPENDENT CLAIM 1**

Independent claim 1 and claims 2, 4-10 and 14-22 which depend therefrom, were rejected as being unpatentable over Estes. Applicant respectfully traverses this rejection with respect to independent claim 1 as amended.

In general, Estes discloses a fixation plate and screw back-out system 10 which comprises fixation plate 12 that has a bore 18 therethrough that is sized to receive a fastening element. Top portion of bore 18 is recessed from the top surface 15 of fixation plate 12 in a semi circular shape to facilitate the seating of the fastening element. System 10 further includes an annular ring 16 having a bore 45 therethrough defining an inner annular surface having a diameter 44. Inner and outer annular surfaces 40 and 34 respectfully terminate at a top end 36 and an opposite bottom end 32. Collar 16 is preferably made of unitary construction and is formed of a material that is responsive to a change in temperature to assume an expanded or retracted shape.

Applicants respectfully submit that Estes does not disclose each and every limitation of independent claim 1. As amended, independent claim 1 recites, *inter alia*, as follows: "an implant for bone fixation comprising: a body having an upper surface and a bottom surface wherein the body is formed of a plastic material at least four openings extending from the upper surface through to the

bottom surface each of which opening is configured to receive a bone fixation device; and at least four peripheral perimeters each of which perimeter is made in the form of a metallic rectangular die; wherein each peripheral perimeter is rigidly inserted into one of the multiple openings.”

Applicants respectfully submit that there is no disclosure, teaching, or suggestion in Estes of an implant having a body with an upper surface and a bottom surface where the body is formed of a plastic material and has at least four openings extending from the upper surface through to the bottom surface and at least four peripheral perimeters each of which perimeter is made in the form of a metallic rectangular die wherein each peripheral perimeter is rigidly inserted into one of the multiple openings.

Specifically, at most Estes teaches an anti-back out fixation system where a collar which is made of unitary construction and is formed of a material that is responsive to a change in temperature expands or retracts in shape to accommodate a screw for securing a fixation plate. This collar cannot be interpreted to be the same as the peripheral perimeters of claim 1 which are made in the form of a metallic rectangular die and are rigidly inserted into one of the multiple openings. There is absolutely no disclosure, teaching or suggestion in Estes for the implant recited in claim 1.

Thus, it is respectfully submitted that, for at least the above-identified reason, Estes does not disclose, teach or suggest all of the limitations of independent claim 1. Therefore, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2, 4-10, and 14-22 depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2, 4-10, and 14-22 is also respectfully requested.

Additionally, independent claim 1 and claims 2, 4-10, 12-15, and 17-22 were rejected as being unpatentable over Eberlein.

In general, Eberlein discloses a fastening assembly 10 for fastening a fixing element such as brace 16 to a substructure 14. The brace has a first bore 32 and a second bore 34 where a first bushing 36 is received in the first bore 32 and a second bushing 38 is received in the second bore 34. Each of the bushings also comprises a seat which is designed to receive a screw. The bushings are mounted in the bores to be able to swivel in several directions until the head of the screw engages the seat of the bushings.

Applicants respectfully submit that Eberlein does not disclose each and every limitation of independent claim 1. As amended, independent claim 1 recites, *inter alia*, as follows: “an implant for bone fixation comprising: a body having an upper surface and a bottom surface wherein the body is formed of a plastic material at least four openings extending from the upper surface through to the bottom surface each of which opening is configured to receive a bone fixation device; and at least four peripheral perimeters each of which perimeter is made in the form of a metallic rectangular die; wherein each peripheral perimeter is rigidly inserted into one of the multiple openings.”

Applicants respectfully submit that there is no disclosure, teaching, or suggestion in Eberlein of an implant having a body with an upper surface and a bottom surface where the body is formed of a plastic material and has at least four openings extending from the upper surface through to the bottom surface and at least four peripheral perimeters each of which perimeter is made in the form of a metallic rectangular die wherein each peripheral perimeter is rigidly inserted into one of the multiple openings.

Specifically, at most Eberlein teaches a fastening assembly with bushings capable of swiveling in various directions. The bushings are mounted into the bore and swivel until the head of the screws engage the seats of the bushing. The bushings disclosed in Eberlein cannot be said to be the same as the peripheral perimeters of claim 1 which are made in the form of a metallic rectangular die and are rigidly inserted into one of the multiple openings. There is absolutely no disclosure, teaching or suggestion in Eberlein for the implant recited in claim 1.

Thus, it is respectfully submitted that, for at least the above-identified reason, Eberlein does not disclose, teach or suggest all of the limitations of independent claim 1. Therefore, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 5, 7-10, and 14-15, depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 5, 7-10, and 14-15, is also respectfully requested.

With respect to claims 3 and 11 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of Eitenmuller, it is respectfully submitted that Eitenmuller does not overcome the short comings of Estes. Additionally the Office Action does not identify where the polygonal external form of claim 3 is found in Estes or Eitenmuller. Without addressing the merits of this argument and/or the combination, it is respectfully submitted that, for at least the above-identified reasons, neither Estes, or Eitenmuller either alone or in combination, disclose, teach or suggest all of the limitations of dependent claims 3 and 11. Thus, it is respectfully submitted that dependent claims 3 and 11 are allowable. Withdrawal of this rejection and allowance of dependent claims 3 and 11 is respectfully requested.

#### **NEWLY ADDED INDEPENDENT CLAIM 24**

Newly added independent claim 24 has been added through this amendment and Applicants respectfully submit that new claim 24 is patentable over the prior art of record. Newly added claim 24 recites, *inter alia*, “a body having an upper surface and a bottom surface wherein the body is formed of a plastic material; one or more sleeve shaped openings extending from the upper surface through to the bottom surface each of which opening is configured to receive a bone fastener; a first peripheral perimeter formed of titanium material; and a second peripheral perimeter formed of titanium material; wherein the first and second peripheral perimeters are joined together and rigidly inserted within the sleeve shaped opening.”

It is respectfully submitted that the cited prior art does not disclose an implant comprising a body having an upper surface and a bottom surface wherein the body is formed of a plastic material, one or more sleeve shaped openings extending from the upper surface through to the bottom surface each of which opening is configured to receive a bone fastener; a first peripheral perimeter formed of titanium material; and a second peripheral perimeter formed of titanium material; wherein the first and second peripheral perimeters are joined together and rigidly inserted within the sleeve shaped opening.

Therefore, it is respectfully submitted that newly added independent claim 24 is allowable over the prior art and its allowance is earnestly requested.

#### **NEWLY ADDED INDEPENDENT CLAIM 25**

Newly added independent claim 25 has been added through this amendment and Applicants respectfully submit that new claim 25 is patentable over the prior art of record. Newly added claim 25 recites, *inter alia*, “a body having an upper surface and a bottom surface wherein the body is formed of a plastic material; one or more sleeve shaped openings extending from the upper surface through to the bottom surface each of which opening is configured to receive a bone fastener; a first peripheral perimeter formed of titanium material and containing a sleeve shaped extension; and a second peripheral perimeter formed of titanium material; wherein the first and second peripheral perimeters are joined together and rigidly inserted within the sleeve shaped opening and wherein the sleeve shaped extension is located above the upper surface of the body and acts as a target aid for the bone fastener.”

It is respectfully submitted that the cited prior art does not disclose an implant comprising a body having an upper surface and a bottom surface wherein the body is formed of a plastic material; one or more sleeve shaped openings extending from the upper surface through to the bottom surface each of which opening is configured to receive a bone fastener; a first peripheral perimeter formed of titanium material and containing a sleeve shaped extension; and a second peripheral perimeter formed of titanium material; wherein the first and second peripheral perimeters are joined together and rigidly inserted within the sleeve shaped opening and wherein the sleeve shaped extension is located above the upper surface of the body and acts as a target aid for the bone fastener.

Therefore, it is respectfully submitted that newly added independent claim 25 is allowable over the prior art and its allowance is earnestly requested.



## CONCLUSION

In view of the forgoing remarks, Applicants respectfully submit that the present application, including pending claims 1, 3, 5, 7, 8-11, 14-16, 24 and 25, is in condition for allowance and such action is respectfully requested.

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicant's attorney at the number listed below.

Respectfully submitted,

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